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E.O. 12958: N/A

TAGS: <u>BEXP</u> <u>ETRD</u> <u>ETTC</u> <u>RS</u>

SUBJECT: EXTRANCHECK: PRE-LICENSE CHECK: M.P.CHUMAKOV INST. OF POLIOMYELITIS MYELITIS, MOSCOW, RUSSIA, LICENSE NO. D366152

REFTEL: USDOC 06044

- 11. Unauthorized disclosure of the information provided below is prohibited by Section 12C of the Export Administration Act.
- 12. Reftel requested a Pre-license check to determine the legitimacy and reliability of the end-user, M.P. Chumakov Institute of Poliomyelitis and viral encefalitides of Russian Academy of Medical Sciences, Moscow, Russia. The company is listed on BIS license application D366152 as the ultimate consignee of a Bioflo-Pro-150L Fermentor. These items are controlled for chemical/biological warfare reasons under ECCN 2B352. The licensee is New Brunswick Scientific Co. Inc., 44 Talmadge Road, Edison, NJ 08818.
- 13. On November 20, 2006, Export Control Attache Donald Pearce and FSN Natalya Shipitsina conducted the requested pre-license check at the offices of M.P. Chumakov Institute of Poliomyelitis and Viral Encefalitides of the Russian Academy of Medical Sciences, Moscow, Leninsky District, Russia. The export control team met with Boris Bykhovsky, Chief Engineer and Galina Belova, General Director.
- 14. The Institute was founded in 1955 for research, development and production of poliomyelitis vaccine. As part of the Russian Academy of Medical Sciences, the Institute today continues this research and production, and has expanded to other viral diseases including encephalitis, yellow fever, hanta, and rabies. The Institute employs over 300, with four Academics of Medical Science (Post-Doctorate), 100 Doctors, and 200 Doctoral candidates. Researchers holding PhD or higher degrees head the laboratories. All of the laboratory facilities are located on the Leninsky District campus. The Institute has collaborated with researchers from the U.S. and other countries since it's inception; Dr. Mikhail Chumakov (for whom the Institute is named) worked closely with U.S. researcher Albert Sabin to bring the first live poliomyelitis vaccine to the Soviet Union. guests are invited to tour and work at the facility on a regular basis. The World Health Organization has certified the labs for the production of vaccines.
- 15. The Institute has been utilizing simian animals to cultivate strains of poliomyelitis for use in producing vaccines. At one time the laboratory had as many as 7000 infected monkeys, from whose kidneys the vaccine was cultivated. Diseases such as HIV and

Ebola complicate the use of monkeys for cultivation of vacceines, and procuring monkeys for medical research has become prohibitively expensive. The cost per monkey in the 1980s was around 120 USD; currently the cost can be 1000 - 1500 USD per monkey.

- 16. The Institute is currently doing small-scale production of vaccines using bioreactor technology. A laboratory utilizing a U.S. made bioreactor has been in operation for several years, and is producing second-generation poliomyelitis vaccine. The Institute is planning on expanding this program based on the success of this operation, in hopes of discontinuing the use of animal hosts. The Institute began negotiations to purchase the fermenter in reftel over a year ago. As the financing for this project is from a Government of Russia program, the procurement must be completed before the end of the calendar year.
- 17. The equipment will be utilized in a laboratory situated in a special building on the campus. As a recipient of government funding, the GOR has audited the security features of the facility prior to authorizing the purchase of the fermenter. A high wall surrounds the campus, and the laboratory building has an inner-perimeter metal fence. Access to the laboratories is limited to authorized personnel, who must pass two checkpoints prior to entering the laboratories. The facility has security officers on duty at all times, and utilizes video surveillance. Eight people are participating in the project, and two will have direct access to the equipment. The Institute plans on purchasing additional units in the future to expand production. Ms. Belova assured the

team that access for Post-Shipment Verification would be granted upon request should one be necessary.

18. Recommendations: Post recommends M.P. Chumakov Institute of Poliomyelitis and Viral Encefalitides of Russian Academy of Medical Sciences, Moscow, Russia, as reliable recipients of sensitive U.S. origin commodities. It is requested that post be notified of final disposition of the application, and of any shipments for this organization in order to conduct appropriate FCS follow-up and statistical reporting. (FCS MOSCOW/SBOZEK/DPEARCE) BURNS